REMARKS

This is intended as a full and complete response to the Office Action dated December 31, 2007, having a shortened statutory period for response extended one month and set to expire on April 30, 2008. Please reconsider the claims pending in the application for reasons discussed below.

Priority

Priority has been claimed to Germany patent application number 102 44 504.4, filed September 25, 2002. The U.S. Patent Office acknowledged receipt of such priority documents. No amendment to the specification is necessary.

Claim Rejections - 35 U.S.C. § 112

Claims 1-29 stand rejected under 35 U.S.C. § 112, second paragraph. In response, Applicants respectfully traverse the rejection.

The term "fast-release" is explained in detail on page 7, line 9 to page 8, line 4, of the specification. Therein, fast-release is defined to indicate that "capsules are able to release the slightly soluble active ingredient present therein within 60 minutes under sink conditions at 37° C." Regarding the Examiner's statement that "the specification does not provide a standard for ascertaining the requisite degree," lines 32 to 39 of page 7 define the release measurement as follows:

> The release time from the capsules will be determined best by a recognized in vitro release test (e.g. according to United States Pharmacopoeia 25), although the apparatus and the conditions must be chosen so that the required sink conditions are maintained. This may mean that a flow cell must be used, instead of the most frequently used paddle apparatus, for certain active ingredients.

Therefore, one of ordinary skill in the art would be apprised of the scope of the claim term "fast-release." Accordingly, Applicants request withdrawal of the rejection and allowance of claims 1, 18, 24 and all claims dependent thereon.

The term "physiologically acceptable," as used to describe excipients, has a definable definition in any dictionary and would be understood on its face to a skilled person in the field of pharmaceutics. To further clarify, excipients claimed as "physiologically acceptable" provide substantially no harmful or adverse effects due to the excipients, which are typically approved by respective authorities. Therefore, the meaning of the term "physiologically acceptable excipients," which the Examiner applied against the references, is clear. Accordingly, Applicants request withdrawal of the rejection and allowance of claims 18-23.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 5, 7, 10, 18, 19 and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Khankari et al.* (US 6,024,981; "*Khankari*") in view of *Caruso et al.* (WO 00/77281; "*Caruso* '281"). Applicants respectfully traverse the rejection.

Claims 1 and 24 recite a dosage and a method in which "fast-release capsules" include a shell "with high permeability for the slightly soluble active ingredient" and "comprising a complex of at least one polyelectrolyte and a counter ion to the polyelectrolyte." *Khankari* describes that particles, which are dispersed in a matrix, may have a protective coating. The protective coating is used to delay onset of bioavailability. Column 7, lines 2-8, of *Khankari* teaches that the coating initially protects a drug by being impermeable for the drug since the coating needs to be disintegrated or dissolved to release the drug. See, also, column 8, lines 13-41. Contrary to the Examiner's statement, rapid-releasing lacks necessitation of high permeability given that the coating disclosed in *Khankari* is impermeable but can be dissolved or disintegrated. A skilled person, when starting from *Khankari*, would therefore not consider a permeable shell. In addition, *Khankari,* as the Examiner states, "fails to expressly disclose the shell of the microcapsules comprising of at least one polyelectrolyte and a counter ion to the polyelectrolyte."

Furthermore, *Caruso* '281 teaches that a polyelectrolyte shell as described therein delays the onset of bioavailability since the polyelectrolyte shell allows a "controlled release" (*i.e.*, not "fast-release" as claimed) of encapsulated material as described on page 11, lines 21-25. The term "controlled release" is synonymous for

sustained or delayed release, as evidenced by *Khankari* at column 6, lines 60-63. *Khankari* distinguishes sustained release dosage forms from rapid release dosage forms at, for example, column 7, line 66, through line 18 of column 8. Hence, even when hypothetically combining teachings of *Khankari* and *Caruso* '281, a skilled person would use, if at all, the polyelectrolyte shell disclosed in *Caruso* '281 only in applications where a sustained-release coating is desired.

Therefore, *Khankari* in view of *Caruso* '281 fails to teach, show or suggest dosages and methods in which "fast-release capsules" include a shell "with high permeability for the slightly soluble active ingredient" and "comprising a complex of at least one polyelectrolyte and a counter ion to the polyelectrolyte," as recited in claims 1 and 18. Further, *Khankari* in view of *Caruso* '281 cannot render obvious any claims dependent on claim 1 or 18. Accordingly, Applicants request withdrawal of the rejection and allowance of claims 1, 5, 7, 10, 18, 19 and 23.

Claims 1-3, 5-10, 18-20, 22-24, 27 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Parikh et al.* (US 2002/0106403; "*Parikh*") in view of *Caruso et al.* (EP 1 116 516; "*Caruso* '516"). In response, Applicants respectfully traverse the rejection.

Claims 1, 18 and 24 recite a dosage and methods in which "fast-release capsules" include a shell "with high permeability for the slightly soluble active ingredient" and "comprising a complex of at least one polyelectrolyte and a counter ion to the polyelectrolyte." *Parikh,* as the Examiner states, "fails to expressly disclose the shell of the microcapsules comprising of at least one polyelectrolyte and a counter ion to the polyelectrolyte." *Caruso* '516, like *Caruso* '281, also uses the term "controlled release." See, paragraph [0032]. There is no indication in either *Parikh* or *Caruso* '516 that proposed modifications would enable controlling the release rate of any hypothetical combination to meet the "fast-release capsules" limitation of the claimed dosage and methods. Rather, a polyelectrolyte coating as described in *Caruso* '516 if hypothetically combined with the teachings of *Parikh* would result in sustained release of encapsulated material, similar to the foregoing discussion of *Khankari* in view of *Caruso* '281.

Therefore, *Parikh* in view of *Caruso* '516 fails to teach, show or suggest dosages and methods in which "fast-release capsules" include a shell "with high permeability for

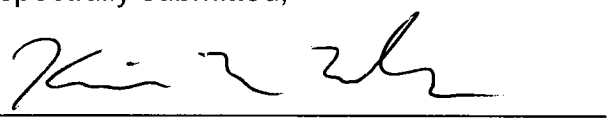
the slightly soluble active ingredient" and "comprising a complex of at least one polyelectrolyte and a counter ion to the polyelectrolyte," as recited in claims 1, 18 and 24. Further, *Parikh* in view of *Caruso* '516 cannot render obvious any claims dependent on claim 1, 18 or 24. Accordingly, Applicants request withdrawal of the rejection and allowance of claims 1-3, 5-10, 18-20, 22-24, 27 and 29.

Claims 4, 25, and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Parikh* and *Caruso* '516 in view of *Green et al.* (US 2001/0055611). Claims 12 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Parikh* and *Caruso* '516 in view of *Virgalitto et al.* (US 2005/0089548). *Green et al.* and *Virgalitto et al.* fail to overcome the deficiencies of *Parikh* and *Caruso* '516 as discussed herein with respect to the independent claims from which claims 4, 12, 21, 25, and 28 depend. Accordingly, Applicants request withdrawal of the rejection and allowance of these claims.

Conclusion

Having addressed all issues set out in the office action, Applicants respectfully submit that the claims are in condition for allowance and respectfully request that the claims be allowed.

Respectfully submitted,



Keith M. Tackett
Registration No. 32,008
PATTERSON & SHERIDAN, L.L.P.
3040 Post Oak Blvd. Suite 1500
Houston, TX 77056
Telephone: (713) 623-4844
Facsimile: (713) 623-4846
Attorney for Applicants